

EXHIBIT 1

Augustine Medical Inc.
Scott D. Augustine MD
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Eden Prairie, MN 55344
612-941-8866
September 14, 1987

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Ave.
Silver Spring, MD 20910

Re: 510(k) Notification

Attention: Document Control Clerk

This is to notify you of the intention of Augustine Medical, Inc. to manufacture and market the following device:

Classification name: System, Thermal Regulating 74-DWJ

Common/Usual name: Hyper/hypothermia system.

Proprietary Name: Bair HuggerTM - Patient Warming System

Establishment Registration Number: Augustine Medical, Inc., has submitted Form FDA 2891 (Initial Registration of Medical Device Establishment) for its manufacturing facility located at the above address.

Classification: Patient warming equipment would most likely have been reviewed by the FDA Cardiovascular (or possibly General Surgery) Classification Panel.

Performance Standard: None established under Section 514.

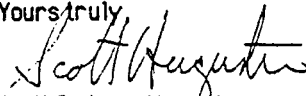
Labeling/Promotional Material: Labeled specimen and draft copies of promotional literature are enclosed.

Substantial Equivalence: This product is similar in design and function to the Sweetland Bed Warmer and Cast Dryer, "For warming patients in shock or chill. Drying plaster casts and warming beds." The Sweetland Bed Warmer was manufactured and marketed by the J.T. Posey Co., from 1937 to 1942. Many of these units are still in active use. See enclosures 1 and 2 for more detail.

We consider our intent to market this device as confidential commercial information and request that it be considered as such by the FDA.

If you have any questions or require additional information or data, please call me at 816-228-2213.

Yours truly,


Scott D. Augustine MD
President and Medical Director

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Bair Hugger
Exhibit 2
Date: 11-2-16
Richard G. Stirewalt
Stirewalt & Associates

3MBH00047858

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Enclosure 1

Bair Hugger™ - Patient Warming System

Description of the product: The Bair Hugger System is designed to treat the discomfort post-operative hypothermia by creating a personalized environment of comforting warm air. The Bair Hugger System consists of two parts; the Heater/Blower Unit (see enclosure 3) and the Bair Hugger™ Patient Cover (see accompanying photographs). The Patient Cover is attached to the air hose by a simple wrap-around tape. The System is then turned "on", and the desired manifold air temperature is selected within the range of 95°-105°-115° F, (corresponds with an average air temperature of 90°-100°-110° F surrounding the patient*). The inflated Bair Hugger Patient Cover is placed over the patient and the blanket or sheet that was covering the patient during transport, is removed and placed over the inflated Patient Cover, to minimize heat loss from the system. The Bair Hugger Cover creates a "micro-environment" of increased ambient temperature, that surrounds and contacts the patient on all non-dependent surfaces except the head. The crucial role of ambient temperature, causing, preventing and treating peri-operative hypothermia, has been documented in numerous clinical reports.

The Bair Hugger™ Patient Warming System, is identical in design and function to the Sweetland Bed Warmer and Cast Drier, J. T. Posey Co (see enclosure 2), with one exception; the Bair Hugger System includes a disposable air cover to deliver the air to the patient. The Cover evenly distributes and confines the warm air to a small space around the patient. Warm air from the Sweetland Bed Warmer is simply blown under the patients blankets, to create a similar environment.

Bair Hugger Heater/Blower Unit:

Size: 26" h x 22.5" w x 14" d (includes storage space for the electrical cord, air hose and extra Bair Hugger Covers).

Weight: 75 lbs (est.)

Electrical Requirements: 115 V, 15 amp, 50/60 Hz, grounded, electrical service.

Major Components:

Blower: Capable of delivering air at 100 cu ft/min to the patient and 2" (H₂O) pressure in the Bair Hugger cover.

Heater: 4-100 W finned tubular heaters, with enclosed heating elements.

Temperature controller: Microprocessor based temperature controller with the sensor in the heater manifold, accurate to +/- 1° F. Temperature range of 95°-115° F in the manifold translates to an average temperature of air delivered to the patient of 90°-110° F, due to heat loss from the hose and Patient Cover (*). The indicated temperature is the manifold temperature and is clearly labeled as such.

Alarm and safety circuits: High temperature safety switch/circuit, shuts the heater and blower off and energizes an audible and visual alarm, in the event of the temperature within the manifold reaching 125° F. This safety circuit is designed to protect the patient in the unlikely event of a simultaneous temperature controller failure in the "on" position and blocked air flow through the hose, over-heating the unit and subsequently delivering the hot air to the patient.

Air delivery hose: 4 ft. of 2.5 in. wire reinforced vinyl hose, allows positioning of the Heater Unit at the end or side, of the foot of the gurney.

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Enclosure 1

Bair Hugger™ Patient Cover:

The disposable patient cover consists of a series of inflatable, heat-sealed polyethylene tubes, adjacently joined along their bottom surface. When inflated, the tubes form an arched structure which "hugs" the patient, is self stabilizing and self supporting. This self supporting design creates a small air space between the Cover and the patient. The patient surface of the Cover has a layer of soft tissue paper thermally bonded to the polyethylene for patient comfort and absorbability. Numerous small holes in the patient surface, allow the warm air to gently blow on to the patient within. Air flows of approximately 100 cu ft/ min then escape from around the patient, primarily out the foot end of the Cover. Air flow past the patients face is minimized by a tissue paper "bib", thermally bonded to the head end of the Cover. Maximum efficiency is achieved when bed cloths are not placed between the Cover and the patient. Additionally, it is recommended that the Bair Hugger Cover be insulated from the ambient room temperature, by placing a sheet or blanket over the top of the inflated cover, to minimize heat loss from the system.

* Bench test data: The thermistor, measuring the delivered air temperature for the temperature controller, is located in the manifold, within the Heater/ Blower Unit. Due to the minimal specific heat of air, there is considerable heat loss from the hose and Bair Hugger Cover before the air reaches the patient. Data collected throughout the range of ambient room temperatures, from 65° - 74° F, shows that the air temperature decreases an average of 1° F along the length of the hose and an additional decrease of 7-8° F occurs between the central air inlet in the Cover, and the outlet holes in the lateral tubes. Significant mixing of the air occurs in the patient compartment, resulting in an average heat loss of 5° F, between the air in the manifold and the air in the patient compartment. The 5° F heat loss from the hose and Cover was measured with the Bair Hugger Cover insulated from the ambient room air by a double layer of light weight cotton blanket (the recommended method of use), similar to the blankets commonly used in hospitals. If a cotton insulating blanket is not used, the temperature of the air delivered to the patient averages 6-8° F less than the indicated temperature. Temperatures were measured with a calibrated Omega dual channel, digital electronic thermometer and thermistors accurate to +/- 0.85° F (Omega Engineering, Inc., Stamford, CT).

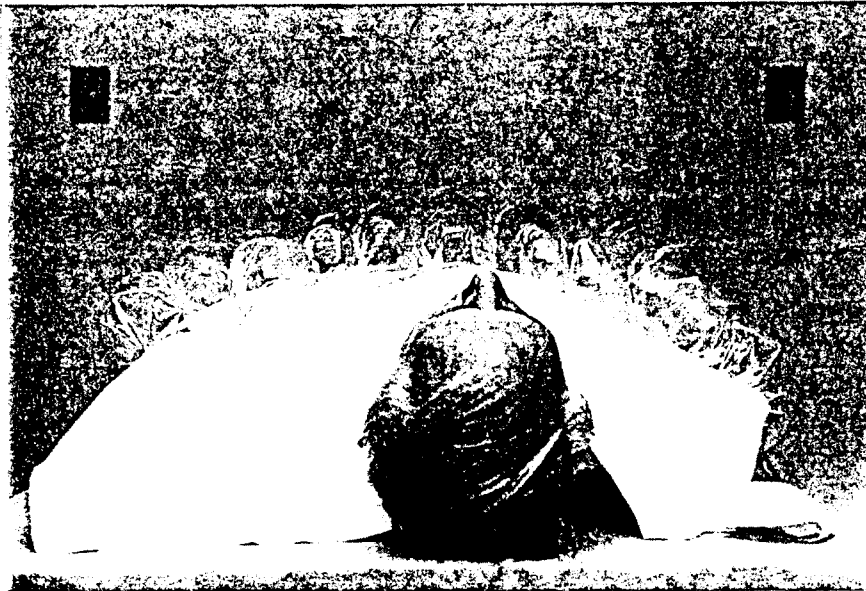
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Enclosure 1

Bair Hugger Patient Cover

Prototype of the inflated air cover showing the positioning over the patient. Also shows the tissue paper (blue) surface in contact with the patient and the paper "bib" which limits the air flow past the patients head.

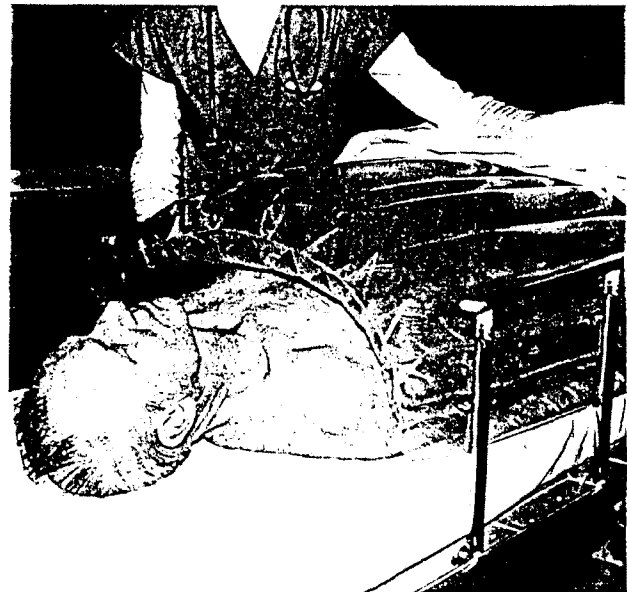
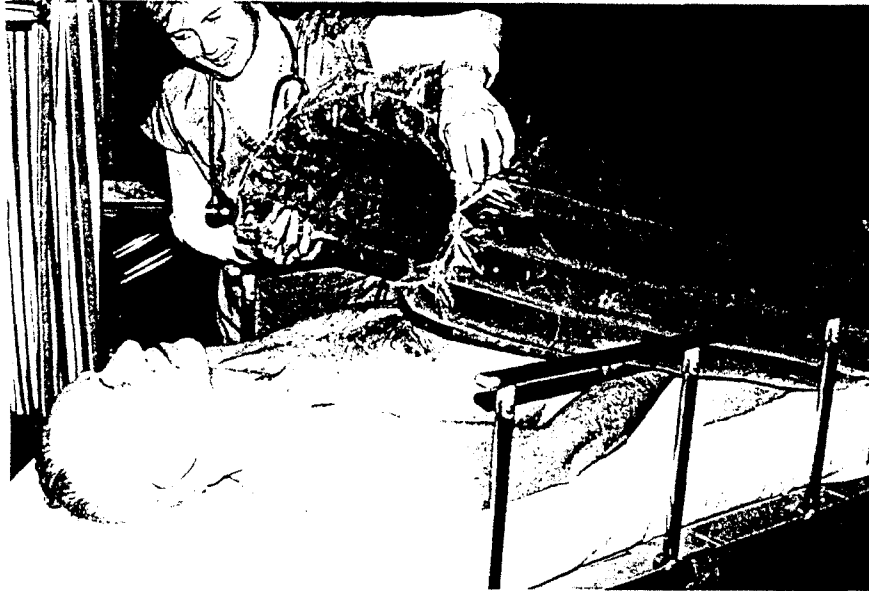
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Enclosure 1

Bair Hugger Patient Cover

Demonstrator prototype of the air cover (does not include tissue paper lining and "bib"). Demonstrates the "hugging" configuration, the self supporting nature and the air space that comprises the patient compartment.

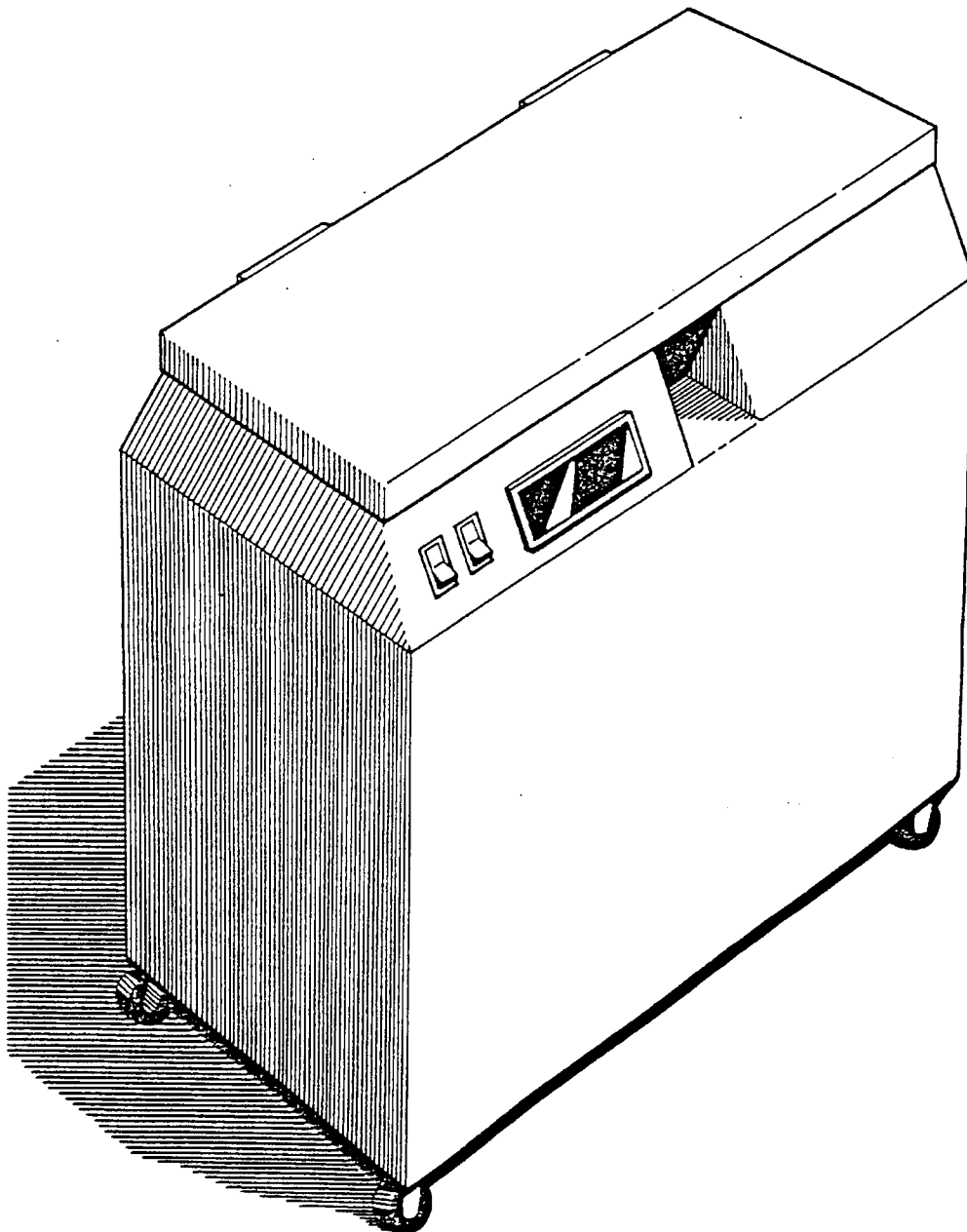


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Enclosure 1

Bair Hugger Heater/Blower Unit- Design drawing

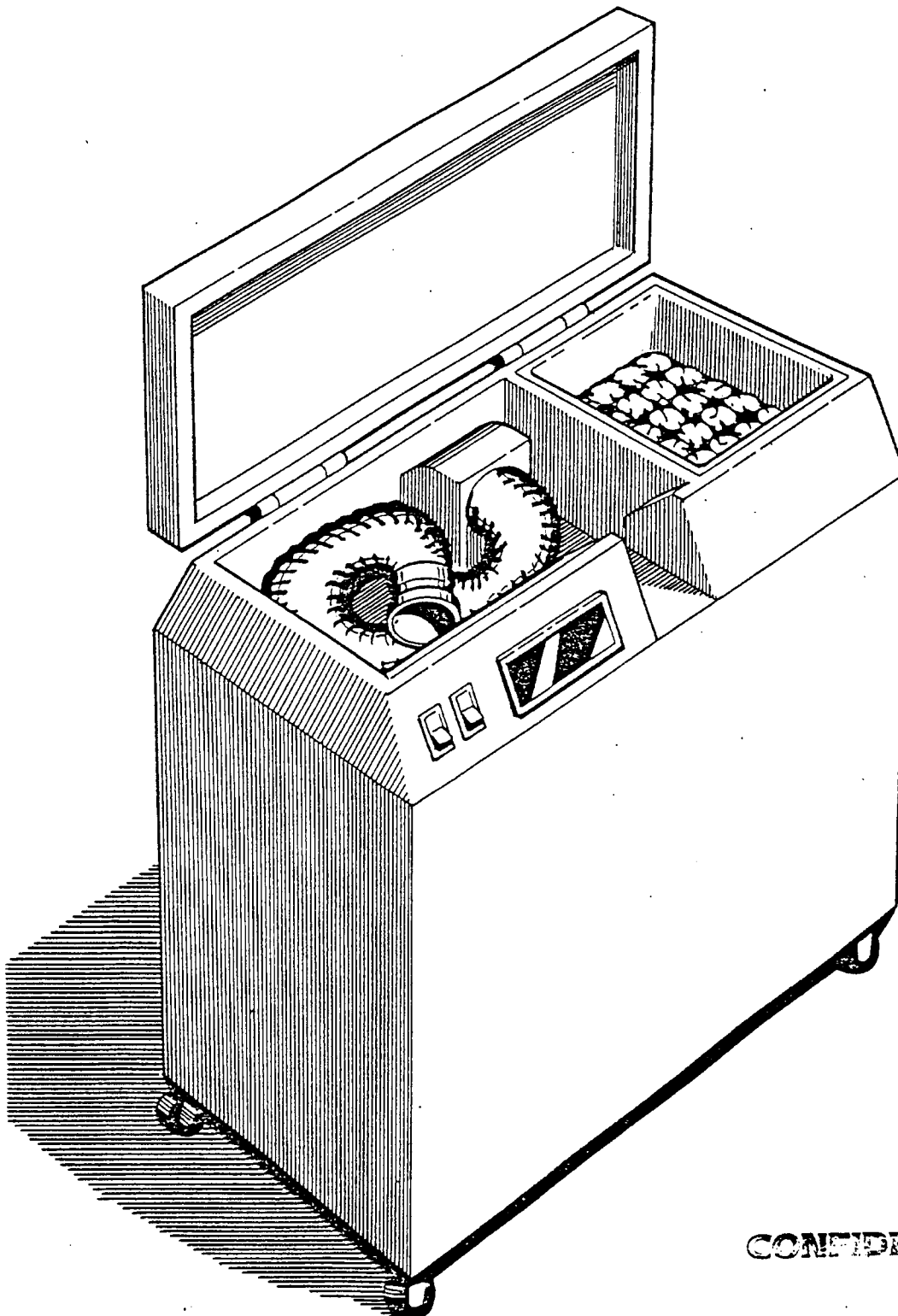


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Enclosure 1

Bair Hugger Heater/Blower Unit- Design drawing



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Enclosure 2

Sweetland Bed Warmer and Cast Drier

"For warming patients in shock or chill. Drying plaster casts and warming beds."

Description of the Product: (No product literature available, see enclosed photographs.) The Sweetland Bed Warmer was invented in 1935 by Ernest Sweetland, U.S. Patent # 2,122,964. It consists of a heater, blower and temperature controller. The warm air exits the unit through a 4" air hose, which is placed under the patients blanket. The blanket partially confines the warm air to a space around the patient. The temperature controller has "Low", "Medium" and "High" settings, "High" being 110° F. Additionally there is a high temperature safety switch set at 136° F, to protect the unit in the event of a blocked hose and no air flow (*).

The Sweetland Bed Warmer was manufactured and distributed by the J. T. Posey Co., 405 Montgomery St., San Francisco, CA, from 1937 to 1942. Many of these units, such as the one pictured, are still in active service treating post-operative hypothermia. There are no known reports of mishap, serious mechanical failure or complications due to therapy with this device(*).

* Personal communication:

Mr. J. T. Posey
President and Founder
J. T. Posey Co.
5635 Peck Rd.
Arcadia, CA 91006
818-443-3143

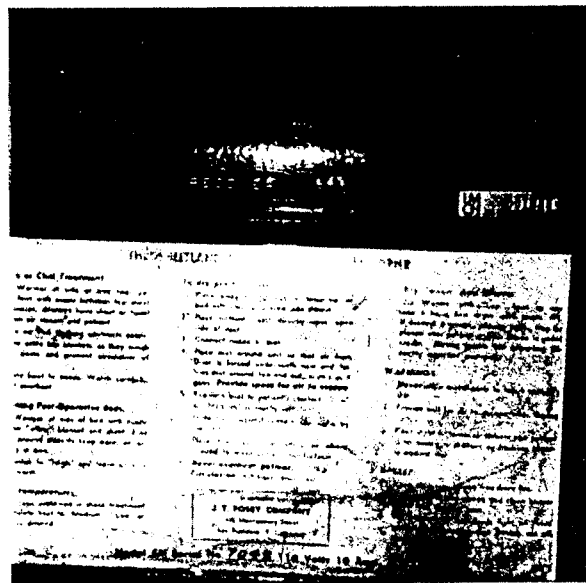
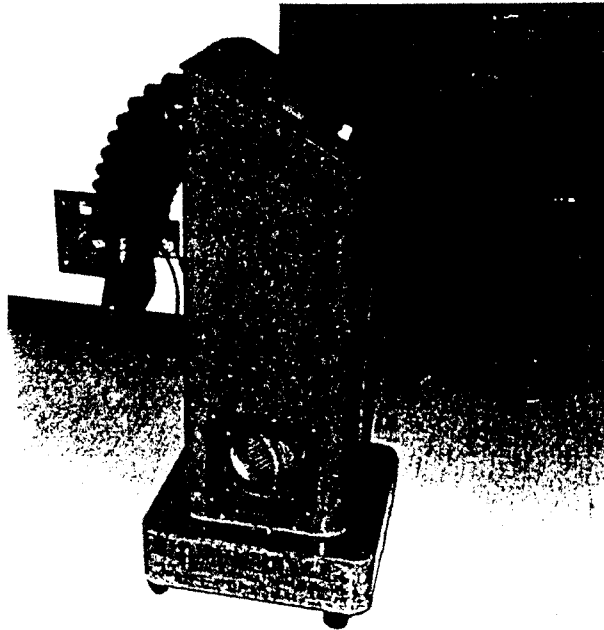
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Enclosure 2

Sweetland Bed Warmer and Cast Drier

The Sweetland Unit showing the blower inlet and discharge hose. Also showing a close-up of the instructions.

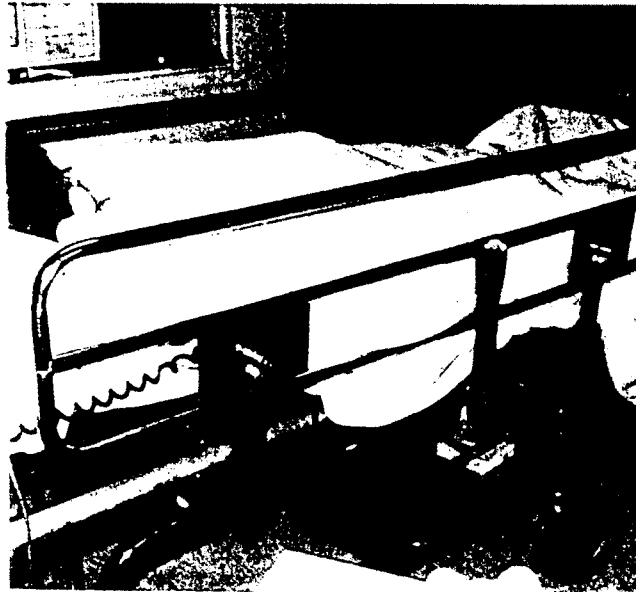
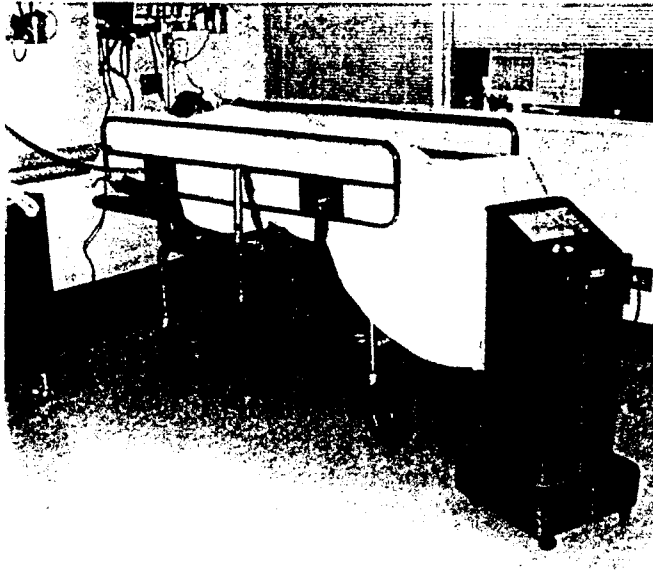
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Enclosure 2

Sweetland Bed Warmer and Cast Drier

The Sweetland Warmer heating a post operative patient.
Notice the inflated appearance of the patients blanket.



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